



CERTIFICATE

EC No 1434-MDD-333/2019
Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

CARDIONOVUM GmbH

Am Bonner Bogen 2
53227 Bonn, Germany

for the design, manufacture and final inspection of medical device
class III

RESTORE DEB Paclitaxel Releasing
PTCA Balloon Catheter

List of devices covered by this certificate is given in the Annex no. 1

was examined in accordance with Annex II excluding p. 4 to Directive 93/42/EEC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 31.05.2019 to 30.05.2024

The date of issue of the Certificate: 31.05.2019



Application No: 251/2018
Module: H2


mgr Anna Wyroba
Vice-President



Certificate No. **1434-MDD-333/2019**
Issued under the Contract No MD-02/2019
Bears the PCBC hologram.
Warsaw, 31.05.2019



ANNEX no. 1 TO CERTIFICATE
VALID ONLY WITH CERTIFICATE
No 1434-MDD-333/2019

The products detailed below are covered under the scope of this certificate:

		Balloon diameter (mm)						
		2.00	2.25	2.50	2.75	3.00	3.50	4.00
Balloon length (mm)	15	R 2.00-15	R 2.25-15	R 2.50-15	R 2.75-15	R 3.00-15	R 3.50-15	R 4.00-15
	20	R 2.00-20	R 2.25-20	R 2.50-20	R 2.75-20	R 3.00-20	R 3.50-20	R 4.00-20
	25	R 2.00-25	R 2.25-25	R 2.50-25	R 2.75-25	R 3.00-25	R 3.50-25	R 4.00-25
	30	R 2.00-30	R 2.25-30	R 2.50-30	R 2.75-30	R 3.00-30	R 3.50-30	R 4.00-30



Anna Wyroba
mgr Anna Wyroba
Vice-President



Annex 1 to certificate No. **1434-MDD-333/2019**
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